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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,649	10/18/2001	Markus Baur	88265-10173	8748
28765	7590	06/16/2004	EXAMINER	
WINSTON & STRAWN PATENT DEPARTMENT 1400 L STREET, N.W. WASHINGTON, DC 20005-3502			LANKFORD JR, LEON B	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/982,649	<b>Applicant(s)</b> BAUR ET AL.	
	<b>Examiner</b> Leon Lankford	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-12 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Applicant's arguments filed 4/1/04 have been fully considered but they are not persuasive. The rejection under 35 USC 103 remains for certain claims.

Claim 8 is allowable.

Claim 13 would be allowable in independent form.

Applicant's disclosed invention appears to be cell lines better than those of the prior art however the instantly rejected claims are not commensurate in scope with applicant's showings in the specification. SV40 immortalized keratinocyte and melanocyte cell lines exist in the prior art. It is also at least prima facie obvious to make more so immortalized cell lines using known methods and viral constructs. Applicant discloses cell lines which are unexpectedly better than the prior art (hence the allowability of claims 8 & 13) however the broader claims rely on the limitation "high passage" to differentiate over the prior art and applicant's definition of this phrase appears to encompass prior art cell lines. While applicant's cells "hold" the desired properties longer than those of the prior art, applicant defines "high passage" as being as few as 10 times and also it is noted that the claims require expression of proteins and that would not exclude the inferior expression of the prior art cell lines.

Applicant's arguments have been considered however a showing to overcome a prima facie case of obviousness must be clear and convincing( In re Lohr et al. 137 USPQ 548) as well as commensurate in scope with the claimed subject matter ( In re Lindner 173 USPQ 356; In re Hyson, 172 USPQ 399 and In re Boesch et al., 205 USPQ 215 (CCPA 1980).

Mr. Fuller is invited to call the undersigned examiner to discuss possible allowable claims.

***Claim Rejections - 35 USC §102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

OR

***Claim Rejections - 35 USC §103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7 & 9-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jetten et al (*J Invest Dermatol* 1989) or Steinberg et al (*J Cell Physiol* 1985) or Hronis et al (*Cancer Res* 1984) or Morris et al (*PNAS* 1985).

4. Applicant claims an retrovirally immortalized cell line.

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1 Jetten et al (*J Invest Dermatol* 1989), Steinberg et al (*J Cell Physiol* 1985), Hronis et al (*Cancer Res* 1984) and Morris et al (*PNAS* 1985) all teach immortalized keratinocyte cell lines. The references are silent on many of the claimed characteristics however as the cell lines share other disclosed properties, it would appear that the reference cell lines would inherently have those properties. Consequently, the claimed cell lines appear to be anticipated by the aforementioned references.

However, even if the reference's cell line and the claimed cell lines are not one and the same and there is, in fact, no anticipation, the reference cell lines would, nevertheless, have rendered the claimed cell lines obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clear close relationship between the cell lines as evidenced by their being the same cell type and their close structural and functional relationship.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not Applicants' cell lines differ and, if so, to what extent, from that discussed in the references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to Applicants.

Note that MPEP § 706.3(e) states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make

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physical comparisons therewith. A lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972) ; *In re Fessmann*, 180 USPQ 324 (CCPA1974)."

Furthermore, Keratinocytes and melanocytes were well known at the time the invention was made as was the SV40 immortalization method. Given that and the motivation/desire to make immortalized cell lines from these cell types which is provided by the two cited reference, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the references, especially in the absence of evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

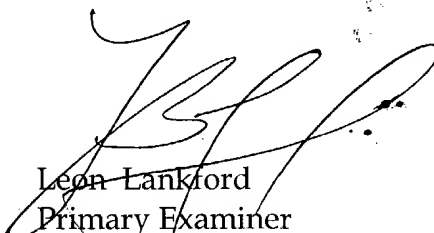
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date

of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leon Lankford  
Primary Examiner  
Art Unit 1651

LBL